

REMARKS

Cancellation of claims 27 and 48 renders the rejection at paragraph 6 moot. No agreement with any allegations of the Office Action is implied.

All of the obviousness rejections hinge on the examiner's allegation that paragraph 0068 of Bates et al. renders obvious the element of the claims: "wherein the concentration of said drug on said surface is up to 5 $\mu\text{g}/\text{mm}^2$." As is well known, in order for an obviousness rejection to stand, the PTO must show how the cited references disclose or suggest all of the elements in a claim. See *FMT inc. v. Yieldup International Corp.*, 349 F.3d 1333 (Fed. Cir. 2003). Bates et al. does not satisfy this legal standard alone or in combination with any of the other references.

Bates' paragraph 0068 discusses ranges of amounts of paclitaxel which can be sprayed onto a stent having a rough and/or textured surface. See, e.g., page 8, column 2, lines 1-5 and 11. There is no mention whatsoever in this paragraph of surfaces which are not roughened (e.g., which are smooth as required in most of the claims of this application) or which are found on medical devices other than stents.

Whereas it is true that Bates et al. does generally discuss application of drugs on other surfaces such as those of balloons, it is not true that a skilled worker would directly take a teaching regarding the amount of drug suitable for a stent to be directly applicable or even suggestive of amounts which are applicable for the entirely different structure of a balloon. As the examiner is no doubt aware stents have dramatically different structures and functions in comparison to those of balloons on balloon catheters. The examiner simply alleges, "but it is clear that the same concentration is contemplated for use with a balloon." No support for this bald contention is contained in the Office Action. See page 5 thereof.

However, of course, the burden is on the PTO to support all of its allegations by reference to prior art documents or via a declaration of the examiner if the facts are within his/her personal knowledge. See in general 37 CFR § 1.104, particularly subsection (d). Since the PTO has failed to provide support or reasons for this allegation on which the rejection is premised, especially in view of the significant differences in structure and

function of stents and balloons, it can be seen that all of the obviousness rejections are untenable. The secondary references are alleged merely to relate to certain other aspects of dependent claims. Since they all depend on the examiner's allegations based on Bates et al., they all fail for the same reasons discussed above.

With respect to paragraph 4 of the Office Action, applicants note that claim 5 does not recite any processing.

Respectfully submitted,

/Anthony J. Zelano/
Anthony J. Zelano, Reg. No. 27,969
Attorney for Applicant(s)

MILLEN, WHITE, ZELANO
& BRANIGAN, P.C.
2200 Clarendon Boulevard, Suite 1400
Arlington, Virginia 22201
Telephone: (703) 243-6333
Facsimile: (703) 243-6410
AJZ:klb

Date: June 3, 2009